

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5, 9, 10, 13, 27-29, 33, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koontz (US 6,022,902). Patent '902 discloses gas plasma treatment of microporous membranes in any shape by a gas mixture including an inert gas, e.g. argon, and a gas providing functional amino groups on the membrane (functional groups), e.g. ammonia (example 3, claims 1-19; abstract, column 2, lines 25-68; column 4, lines 1-30; column 7, lines 16-19, and lines 37-through column 8, line 7). Patent '902 fails to disclose "regioselective affinity", as defined in the specification (providing more functional groups in one region than another of the surfaces of the membrane), which allows to provide the amino groups in on the surface interest. Patent '902 teaches providing all the surfaces with the amino groups including the pores and exterior surface (abstract). Patent '902, further teaches how to apply the process to a particular degree, by controlling the plasma discharge process, e.g. controlling the diffusion relaxation time (column 12, second paragraph); The time of application depends on the sample (membrane) thickness, and the treatment of a second membrane surface is dependent also on the pressure of application, and temperature

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affecting the pressure of the gases (column 12, third paragraph). Correlations are described in the patent to determine dose rate application based on these parameters (column 13, lines 7-column 15, line 29, and column 15, lines 40-54). It would have been obvious to one skilled in this art based on these teachings to predict that by reducing the exposure time, and increasing the membrane thickness partial functionalization (regioselectivity) can be provided by the treatment for a particular purpose (see column 15, lines 40-54).

3. The use of the functionalized membrane in purification of bio-chemicals is disclosed in the patent (abstract, column 2, lines 19-23). As to claims 2-3, microporous membranes with pore size of 1-2000 microns (column 23, claims 8-9, column 6, third paragraph, and column 7, second paragraph).

Regarding claim 5, providing the functional groups at the interior and exterior surfaces is also disclosed (column 16, last paragraph). The carrier gases and relative gases are disclosed (see column 7, last paragraph bridging column 8).

The process of making the membrane discussed above result in a membrane having the properties of claims 27-29, and 38. The adsorption properties of claim 33 are inherent of the functionalized membrane containing the amino groups, as discussed above. As to claim 39, the carrier gases as discussed above in the discussion of claim.

3. Claims 1-7, 9, 10, 13, 14, 41,15, 22, 26, 27,28, 29, 30-33, 38, 39, 41, 43, 45, 47, 49, 50, 51, 52, 53, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (US 6,245,537). Patent '537 discloses an affinity membrane having affinity for blood or other biologically active fluids and the process of treating the

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membrane with gas plasma in the presence of a gas mixture comprising a modifying gas, to provide modifying functional groups onto the membrane surface, as claimed in claim 1 (abstract, column 3, lines 41-62; column 13, lines 2-31; column 7, lines 25-40, column 8, lines 20-48; column 9, lines 53-68; and column 16, lines 56-64).

Patent to Williams et al ('537) fails to teach the membrane as "microporous"; the patent instead produces porous sizes between 80 to 180 microns (column 23, lines 22-28), or between 20 and 200 microns (column 22, line 68-page 23, line 6). Patent '537, however, suggests making the membrane with a desired pore size, e.g. small enough to block out cells and tissue matter (column 12, 13-17), and further teaches controlling the porosity by selecting a leachable material with different particle size, in the process of making the membrane by solvent casting. This patent teaches tailoring the treatment to meet an specific need (column 10, second paragraph). One skilled in the pertinent art at the time this invention was made following the suggestions in patent '537 would have been motivated to make membranes of lower pore size to provide a lower degree of retention for a desire intended purpose, by using a leachable material (pore former) with lower particle size. It would have been also obvious to one skilled in the art at the time this invention was made to obtain a product or membrane treated by controlling process application, such as time of application, rate of plasma treatment and product thickness and pore thickness to reach to a partial or total functionalization of the product with the amino groups by the gas of gas mixture. As to claims 2-3, the patent teaches the flat (film) configuration and a tubular configuration, and the membrane provided on to a support (column 13, lines 10-13; column 23, lines 34-38). Using a support in tubular

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configuration or hollow fiber would have been obvious to the skilled artisan at the time this invention was made, based on the "tubular" configuration suggested in this patent. Limitations of claims 4-7 and 9, are further disclosed (column 7, lines 26-55; column 8, lines 20-53; column 9, lines 27-68).

Regarding claim 10, the carrier gas and gases combination is disclosed in this patent (column 9, lines 63-66).

As to claim 13, the treatment includes at least one step treatment, which covers the lower range of "up to 10 cycles".

As to claim 15, the application of plasma treatment is not limited to a particular surface; treating the "polymer" (membrane) is disclosed, which suggest all the surfaces (column 9, last paragraph).

Limitations of claims 27-33 and 38 correspond to resulting modified membrane, discussed above; the peptides and amino groups are disclosed in the references (column 7, lines 28-32; column 8, lines 44-46).

In regard to claim 39, nitrogen is added during the plasma treatment (see column 25, 7-8).

As to claim 43, the term bundle is not disclosed, however, as discussed above membranes with tubular configuration, and provided on a desire configuration support is disclosed; the term "up to 1000 fibers" includes a single fiber.

The membrane thickness, claim 45, is further disclosed in the patent above (column 13, lines 9-10)

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As to claim 47, the device is an inherent detecting device, since compounds from blood are attached to the functional groups provided on the membrane material or porous functionalized materials. As to claims 51-54, the reaction between the blood and biological fluids with the functionalized porous material is discussed above.

As to claims 14, 22, 26, and 41, providing the membrane into a housing for performing the gas plasma treatment is not disclosed in the reference. One skilled in the art at the time this invention was made can predict that functionalization, by gas plasma as disclosed in this patent, can be expected when contacting the membrane surface with the mixture of gases under the conditions disclosed in patent '537, independently of whether the membrane is provided within a housing or on a supporting frame, or other structure that allows the surface to be in contact with the gas reacting mixture.

***Allowable Subject Matter***

4. Claims 8, 11, 12, 16-21, 23-25, 40, 42, 44, 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: Combination of limitations as claimed in the objected claims is not disclosed or suggested in the prior art of record. Performing the gas plasma functionalization of the membrane surface at the claimed conditions is not suggested or disclosed in the prior art of record.

4. Applicant's arguments filed 1/4/08 have been fully considered but they are not persuasive. Applicant arguments about the "regioselective affinity" (or partial modification of the membrane, leaving one of the membrane faces no-modified by the treatment) are addressed in the rejection discussed above. Rejection under 102 is changed to 103(a), because although the final product in patent '902 is intended to be functionalized by the plasma treatment at all the membrane surfaces, the patent teaches how to obtain a membrane partly modified by the treatment and what parameters need to be changed to obtain such modification; Details are discussed in the paragraphs above. Patent '537 also teaches tailoring the process to control the degree of modification or the product or membrane, as discussed in the rejection above. For the above reasons, the later rejection is maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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